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Corporate Compliance Programs

How can we make them more effective?

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What does DOJ expect of Board and Management?

- **Delaware law**

- *In re Caremark Int'l Inc. Derivative Litig.*, 698 A.2d 959 (Del. Ch. 1996)
- *Stone v. Ritter*, 911 A.2d 362 (De. 2006)

- **Federal Law, Regulation and Guidelines**

- Reg. S-K Item 406, mandated by SOX §406
- U.S. Sentencing Guidelines
- Securities and Exchange Commission *Seaboard* Report
- U.S. Department of Justice Principles of Federal Prosecution of Business Organizations
- Memorandum from DAG Sally Yates on Individual Accountability for Corporate Wrongdoing
- U.S. Department of Health and Human Services Guidelines on Corporate Responsibility and Corporate Compliance

Origin and Scope of Duties—Delaware Law

In re Caremark Int'l Inc. Derivative Litig., 698 A.2d 959 (Del. Ch. 1996)

- Directors have an obligation to attempt in good faith to assure that:
 - (1) a corporate information and reporting system, which the board concludes is adequate, exists, and
 - (2) this system is sufficient to assure that appropriate information regarding organizational compliance with applicable laws will come to the board in a timely manner and in the ordinary course.
- The level of detail that is adequate for such an information and reporting system is a matter for the board's business judgment.

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Origin and Scope of Duties—Delaware Law

Stone v. Ritter, 911 A.2d 362 (Del. 2006)

- Affirmed the Caremark standard as the basis for assessing director oversight liability, while reconceiving the *Caremark* duties to be consistent with the duty of good faith and loyalty.
- A breach of the monitoring duty occurs when the board either
 - (1) utterly fails to implement any reporting or information system or controls, or
 - (2) if having implemented such system or controls, consciously fails to monitor or oversee its operations thus disabling themselves from being informed of risks or problems requiring its attention.

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Origin and Scope of Duties—Federal Law

- **Reg. S-K Item 406, mandated by SOX §406**
 - Require company to disclose whether it has adopted a code of ethics that applies to the registrant's principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions.
 - The term “code of ethics” means written standards that are reasonably designed to deter wrongdoing and to promote, inter alia,
 - Honest and ethical conduct
 - Compliance with applicable governmental laws, rules and regulations

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Origin and Scope of Duties—Federal Law

- **United States Sentencing Guidelines, U.S.S.G. § 8B2.1**
 - Enable companies to reduce penalties through exercise of due diligence to prevent and detect criminal conduct, and otherwise promote an organizational structure that encourages ethical conduct and a commitment to compliance with the law.
 - 2004 Amendments:
 - An effective compliance program means, at a minimum that “[t]he organization’s governing authority shall be knowledgeable about the content and operation of the compliance and ethics program and shall exercise reasonable oversight with respect to the implementation and effectiveness of the compliance and ethics program.”
 - U.S.S.G. § 8B2.1(b)(2)(A).

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Origin and Scope of Duties—Federal Law

- **United States Sentencing Guidelines, U.S.S.G. § 8B2.1**

- 2010 Amendments:
 - Effective compliance program means that “Individual(s) with operational responsibility shall report periodically to high-level personnel and, as appropriate, to the governing authority, or an appropriate subgroup of the governing authority, on the effectiveness of the compliance and ethics program.
 - To carry out such operational responsibility, such individual(s) shall be given adequate resources, appropriate authority, and direct access to the governing authority or an appropriate subgroup of the governing authority.”

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Origin and Scope of Duties—Federal Law

- **SEC *Seaboard* Report, Release No. 44969, Oct. 23, 2001**

- Among factors considered by SEC in determining appropriate enforcement action, and how to credit self-policing, self-reporting, remediation and cooperation are the following:
 - What processes did the company follow to resolve issues involving potential corporate misconduct?
 - Were the Audit Committee and the Board of Directors fully informed? When?
 - Did the company commit to learn the truth, fully and expeditiously? Did it do a thorough review of the nature, extent, origin and consequences of the conduct and related behavior? Did management, the Board or committees consisting solely of outside directors oversee the review?
 - Were scope limitations placed on the review? If so, what were they?

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Origin and Scope of Duties—Federal Law

- **Department of Justice Guidelines, U.S.A.M. § 9-28.900**

- DOJ prosecution guidelines for organizations require consideration of, among other things, the existence and effectiveness of the corporation's compliance program:
 - Is the corporation's compliance program well designed?
 - Is the program being applied earnestly and in good faith?
 - Does the corporation's compliance program work?
 - Has the corporation established corporate governance mechanisms that can effectively detect and prevent misconduct?
 - Do the corporation's directors exercise independent review over proposed corporate actions rather than unquestioningly ratifying officers' recommendations?
 - Are internal audit functions conducted at a level sufficient to ensure their independence and accuracy?
 - Have the directors established an information and reporting system in the organization reasonably designed to provide management and directors with timely and accurate information sufficient to allow them to reach informed decisions?

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Origin and Scope of Duties—Federal Law

- **Memorandum from DAG Sally Yates, Sep. 9, 2015**

- DOJ to focus on individual accountability for corporate wrongdoing
 - Target must provide all relevant facts about all individuals responsible for the misconduct in order to be eligible for any cooperation credit
 - Both criminal and civil investigations will focus on individuals from the start
 - DOJ will not release culpable individuals from liability absent extraordinary circumstances
- DOJ has high expectations regarding:
 - Remedial measures to stop ongoing or recurring violation
 - New policies or procedures
 - New training
 - Dissemination of compliance materials
 - Employee discipline
- Cooperation with DOJ regarding individuals responsible for violations

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Origin and Scope of Duties—Federal Law

- **HHS-OIG Guidelines**

- *Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors*
 - Affirms the *Caremark* standards
 - States that the duty of care involves determining whether directors acted
 - (1) in good faith,
 - (2) with that level of care that an ordinarily prudent person would exercise in like circumstances, and
 - (3) in a manner they reasonably believe is in the best interest of the corporation.

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What does HHS-OIG consider “Effective”?

- Is the compliance program a mere paper program? Or is it designed, implemented, reviewed, and revised, as appropriate, in an effective manner, under the ongoing oversight of Board/Management?
- It should contain:
 - Written **policies and procedures** including a comprehensive code of conduct describing a clear commitment to corporate integrity and compliance;
 - A **compliance officer** and compliance committee with authority to monitor and enforce standards;
 - **Reporting channels** to the compliance officer, including a “hot line;”
 - Effective compliance **training** programs throughout the organization;
 - A systematic **auditing** plan;
 - **Internal investigation and enforcement** using publicized disciplinary guidelines; and
 - Prompt **corrective action** plans for identified violations.

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Every health care company has a compliance program...

Why do they keep getting investigated and prosecuted?

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The Seven Deadly Sins of Non-Compliant Companies

- 1. Compliance is viewed as a “check-box” exercise.**
- 2. Compliance doesn’t get in on the ground floor.**
- 3. Information is not shared.**
- 4. Compliance is viewed as a drag, not a profit center.**
- 5. Growth is exalted over compliance.**
- 6. Risk tolerance increases over time.**
- 7. Whistle blowers are ignored.**

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1. Compliance is viewed as a “check box” exercise.

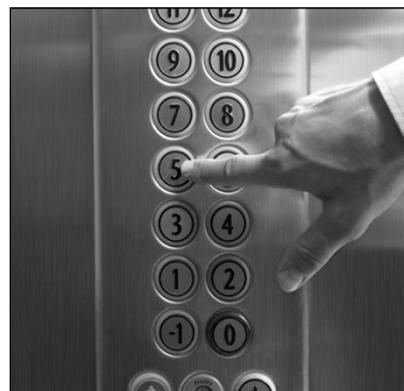
- You are wasting your money on a compliance program if its is merely a beautiful binder of documents, or list of platitudes on a page in the company’s website.
- A “paper” program is more dangerous than no program at all—
 - It gives a false sense of confidence
 - It sets a bar for the behavior that is expected that will be used against you by the Government
- Compliance must be something that everyone in the organization understands is part of the company’s DNA:
 - Exemplified by management, who set the “tone from the top”
 - Lived out by everyone from the most senior managers to the lowliest clerks and custodians
- It is your job to foster a culture of compliance!



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2. Compliance doesn’t get in on the ground floor.

- As soon as you identify a legal or regulatory problem that has the potential to attract law enforcement scrutiny—even if that scrutiny is remote—the compliance team should be called in.
 - Part of an effective compliance program is being able to “triage” problems at the earliest possible point (and being flexible enough to adjust if circumstances change):
 - Is this a **legal** issue (do we need in-house, or outside counsel)?
 - Is this a problem for the **compliance** officer/team to investigate and remedy?
 - Is this a **human resources** issue that can be handled through appropriate channels?
- If compliance can’t perform this essential function, the opportunity to stop non-compliant conduct, prevent a significant overpayment, or conduct an appropriate investigation under the protection of the attorney-client privilege may be lost.



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3. Information is not shared.

- When information is “siloes” or “stove-piped,” everyone is at risk.
- Compliance has to have the “**BIG PICTURE**”—a comprehensive overview of all revenue generating operations and regulated activities.
- Legal/Compliance have to be involved in any decisions that have potential impact on:
 - Billing
 - Reimbursement
 - Arrangements with physicians, hospitals, labs, pharmacies, drug companies, therapy service providers, and any other provider of services to Medicare or Medicaid
 - Handling of controlled substances
 - Discounts
 - Leases
 - Etc.



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4. Compliance is viewed as a drag, not a profit center.

- In many organizations, investments in compliance, legal and regulatory functions are deferred or avoided altogether based on a perception that they do not contribute to a favorable bottom-line.
- **Compliance is an insurance policy.**
- It is a means of cost-avoidance that *does* contribute to profitability over the long term. The costs of defending a single government investigation or the payment in one False Claims Act case can easily wipe out many years of perceived savings from an under-resourced legal and compliance team.
- A health care provider in which the sales team is at war with the clinical, regulatory, or compliance teams is inviting government scrutiny.



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5. Growth is exalted over compliance.

- A common tendency, especially for small companies, start-ups, and other organizations in their infancy, is to dedicate resources to revenue-generating activities, and skimp on legal, regulatory, and compliance resources.
 - **This has medium and long-term risks!**
- Compliance, legal and regulatory functions should have an equal voice in the organization—especially during periods of rapid growth.
- The tendency to avoid investments in compliance when a company is still operating in the red is fraught with legal peril.



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6. Risk tolerance increases over time.

- A similar risk for established companies is the tendency towards accepting incrementally greater risk as time goes by.
- The increased risk may be imperceptible until it is too late.
- It is the role of compliance to question assumptions, do a “root cause” analysis when something goes wrong, and ask why certain practices persist despite contrary industry, regulatory, or other authoritative guidance.
- Beware of anyone whose rationale, when questioned, is:
 - **“We’ve always done it that way”**
 - **“All of our competitors are doing it,”** or
 - **“We can’t make money if we do it your way.”**



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7. Whistle blowers are ignored.

- If there are no channels for employees to raise compliance concerns, or if those employees who do make complaints are **marginalized**, treated as **pariahs**, or otherwise subject to **retaliation**, you should be assured that they will become government whistle blowers.
 - Create a culture in which all voices are treated with respect—even those of the hyper-vigilant.
 - Make sure that there is feedback for anyone who makes a complaint—anonously or not—so that they know what the ultimate disposition of their complaint may be. Whether the complaint is right or wrong, let the employee know!
 - Reward those who blow the whistle internally on practices that potentially put the organization at risk. Show your employees that you value compliant behavior, and encourage them to “raise their hands” when they have questions or concerns.



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Introducing Mike Theis

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Mike Theis handles federal and state False Claims Act litigation, government investigations and white collar criminal defense. Before joining Hogan Lovells, Mike was, from 1997-2005, the Health Care Fraud Coordinator in the United States Attorney's Office in Denver, Colorado, and prosecuted both criminal and civil fraud cases as an Assistant U.S. Attorney. He was a Trial Attorney in the Fraud Section, Commercial Litigation Branch, Civil Division, Department of Justice in Washington, D.C. from 1988-1997. He has personally handled scores of cases filed under the *qui tam* provisions of the False Claims Act, both as Government and defense counsel, including:

- *United States ex rel. Baer v. Ludden*, 2016 WL 1259432 (W.D. Wis. 2016)
- *United States ex rel. Ruotsinoja v. Board of Governors of Colo. State Univ.*, 43 F. Supp. 3d 1190 (D. Colo. 2014)
- *United States ex rel. Raynor v. National Rural Utilities Co-op. Finance Corp.*, 690 F.3d 951 (8th Cir. 2012)
- *United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295 (3d Cir. 2011)
- *United States ex rel. Ellard v. Medtronic Inc.*, 371 Fed. Appx. 460, 2010 WL 1141636 (5th Cir. 2010)
- *United States ex rel. Pfeifer v. ELA Medical, Inc.*, 2010 WL 1380167 (D. Colo. 2010)
- *LeBlanc v. United States*, 50 F.3d 1025 (Fed. Cir. 1995)
- *United States ex rel. Siller v. Becton Dickinson & Co.*, 21 F.3d 1339 (4th Cir. 1994)
- *Mortgages, Inc. v. United States Dist. Court for Dist. of Nev.*, 934 F.2d 209 (9th Cir. 1991)
- *United States ex rel. Burr v. Blue Cross and Blue Shield of Fla., Inc.*, 882 F.Supp. 166 (M.D. Fla. 1995)